

## REMARKS

As required by the Examiner, the term “Mozzarella Cheese” has been amended to remove capitalization. Claim 1 has been amended to incorporate the molecular mass and the feature of Claim 9, which has been cancelled, so as to recite the structure of exopolysaccharide produced by the claimed strain. Support for this amendment can be found in Claim 9 as originally filed and page 9, lines 3-20. In particular, support for the molecular mass limitation can be found on page 9, line 9 of the specification as filed. In addition, some of the withdrawn claims have been amended or cancelled such that all the withdrawn claims are in a form suitable for rejoinder upon allowance of the elected claims. The following addresses the substance of the Office Action.

### Anticipation

The Examiner rejected Claims 1, 2, 4, 5, and 19-21 in the alternative as being either anticipated under 35 U.S.C. § 102(b) or rendered obvious by Lemoine et al. (US 5,965,127) or Faber et al. 1998 *Carbohydrate Research* 310:269-276. Since the issues raised by the two alternatives are distinct, Applicants will first address the anticipation aspect of the rejection by showing that the strains of *S. thermophilus* taught in the prior art are different from the strain presently claimed.

As an initial matter, Applicants note that the Examiner appears to acknowledge the novelty of Claims 3, 32-35 and 39 by not including these claims in the novelty rejection. Accordingly, these claims will be addressed solely from the point of view of obviousness. The novelty of the remaining claims is addressed below:

The Examiner concluded that the strains of the Lemoine and Faber references “appear to be identical to the presently claimed strain, based on the fact that the prior art strain is a member of the same species and that the prior art strain produces a heteropolysaccharide having a molecular weight of at least  $2*10^6$  Dalton” (Office Action, pages 4-5, bridging sentence). Through the use of the word “appear,” the Examiner acknowledged that Applicants have an opportunity to rebut the allegation of identity through presentation of countervailing evidence.

So as to clarify one of the differences between the claimed strain and the strains produced by the Lemoine reference, Claim 1 has been amended to recite the structure and the molecular mass of exopolysaccharide (EPS) produced by the claimed strain. The Examiner indicated that there is no evidence to demonstrate that the Lemoine strain cannot also produce the same EPS as that disclosed by the claimed strain. However, the present applicants discovered that the

monomer composition of the EPS produced by the claimed strain was not influenced by growth conditions. See Applicants' specification at page 8, lines 33-35. Thus, one would not expect subjecting the strain of Lemoine to produce a different EPS, such as that produced by the presently claimed strain, under different culture conditions.

Moreover, the Lemoine strain was in fact used under nearly identical fermentation conditions to those used in the present invention. The following table compares the culture conditions used by Lemoine with those disclosed in the present specification

Lemoine		Present Specification	
10% skim milk powder	Col. 3, lines 56-57	10% skim milk powder	Page 17, lines 20-21
Supplemented with amino acids	Col. 3, lines 57-58	Supplemented with various protein digests (i.e. amino acids)	Page 17, lines 22-23
pH 5.0	Col. 3, line 63	pH 5.1 tested	Page 22, line 11
40°C	Col. 3, line 65	42°C	Page 22, line 18

As can be seen from the table, the culture conditions used were nearly identical. The only significant difference between the two cultures was the strains used. However, the EPS isolated from each culture was completely different. For example, the repeating unit disclosed by Lemoine et al. as illustrated at column 5, 2<sup>nd</sup> full paragraph is different from the repeating unit disclosed in the present application illustrated at page 9, lines 14-19 of the Specification as filed, and now recited in all of the pending claims through the amendment to Claim 1. The repeat structure illustrated by Lemoine et al. has a non-reducing terminal  $\beta$ -Galp (F) residue, while the repeating unit disclosed in the present application does not have such a terminal sugar residue at the analogous position. It can be seen that the strain-specific differences affect the sequence of sugar residues, the degree of branching, and the types of linkages between the sugar residues in the heteropolysaccharide.

Further, the present strain produces an EPS having a molecular mass of at least  $5 \times 10^6$  Daltons which is larger than reported for Lemoine's strain.

If the Lemoine strain were the same as the present strain, it would produce the same EPS under the similar cultural conditions used. In view of the different EPS produced from near identical culture conditions, it is clear that the strain used by Lemoine and the strain identified in the present application are different strains.

Although the two strains disclosed by Faber et al. may produce an EPS similar in structure to that produced by the claimed strain, this does not imply that either of the Faber

strains are the same strain as that presently claimed. As previously discussed, while the two Faber strains produce the same EPS, these two strains are very different from each other. As stated in the abstract: "the only clear difference between both strains . . . is the difference in molecular mass of the polysaccharide." Thus, Faber recognized that differences in the molecular mass of the EPS produced can be used to differentiate different strains of *S. thermophilus*.

In the present case, the claimed invention has a difference in the molecular mass produced from that produced by either of the Faber strains.

As now recited in the claims, the molecular mass of the EPS produced by the present strain is at least  $5 \times 10^6$ . In contrast, the two strains disclosed by Faber produce EPS having smaller molecular mass of  $2.6 \times 10^6$  and  $3.7 \times 10^6$  Daltons, respectively. Faber was able to conclude the presence of two different strains from the approximately 50% difference in molecular mass produced by the two different strains. The present strain produces an EPS having a much larger molecular mass. From this difference in the molecular mass of the EPS produced, it is clear that the present strain is a different strain from either of the Faber strains.

In view of the above remarks, the subject of claim 1 and dependent claims thereof are not anticipated by either Lemoine or Faber.

#### Obviousness

As discussed above, the presently claimed strain is a different strain from the strains of the cited prior art. Moreover, the difference in strains is a nonobvious difference in view of the significant unexpected results obtained using this strain. In particular, the EPS obtained by the present invention has both a high molecular mass and very high stability. As pointed out in Applicants' previous response, the unexpected stability is referred to throughout the specification as filed, for example in the title of the application, at page 1, line 6; page 5, line 18; and page 8, line 33-page 9, line 5; and Figure 5, which shows a distinct peak of the pure EPS with negligible or no degradation into lower molecular mass products.

*Streptococcus thermophilus* ST 111 produces a high molecular mass EPS that is exceptionally stable over time. Referring to page 8, lines 33-35, the monomer composition of the high molecular mass exopolysaccharide produced by *S. thermophilus* ST 111 is not influenced by the physical growth conditions, such as pH of medium and temperature. Moreover, there is no or negligible degradation into lower molecular mass products over time. This high molecular mass advantageously permits production of better yoghurts, having a better consistency (higher

viscosity) with little or no synerese (water releasing) activity. There is no need for adding additional fat free dry weight materials to arrive at a suitable viscosity for the prepared products.

The exceptional stability of the exopolysaccharide produced by *S. thermophilus* ST 111 is an unexpected result since there is no suggestion, let alone teaching in Faber et al. or Lemoine et al. or any other reference that stable, high molecular mass EPS can be obtained by any *Streptococcus thermophilus* strains. Thus, the cited references do not provide any reason to search for additional strain(s) capable of producing exopolysaccharide that have the exceptional stability observed with *S. thermophilus* ST 111. Even if such a reason were present, it is completely unexpected to obtain the presently claimed strain which has such unexpected properties in terms of its consistent production of stable, high molecular mass EPS across a wide range of culture conditions, as well as in the unexpected stability and high molecular mass of that EPS. The EPS produced by the claimed strain provides the further unexpected results described above when used in connection with the production of fermented dairy products. In view of these many completely unexpected results, any *prima facie* showing of obviousness would be rebutted. As such, the presently pending claims are nonobvious over Faber and Lemoine.

Claims 1-5, 19-21, 32-35 and 38-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lemoine et al. or Faber et al. in view of Cravero (US 6,033,691). In view of the significant unexpected results described above, the addition of Cravero does not add anything that would render these claims obvious. Cravero discloses a method for the preparation of a biologically active milk product using a co-culture of Lactobacillus strains and a *Streptococcus thermophilus* strain. However, for the same reasons discussed above, (*i.e.*, the unexpected results, including the exceptional stability of the exopolysaccharide produced by *S. thermophilus* ST 111), the claims are not obvious in view of the cited references. The cited references do not provide any reason to search for additional strain(s) capable of producing exopolysaccharide that have the exceptional stability observed with *S. thermophilus* ST 111. Thus, the claims are not obvious in light of the cited references and removal of the rejection is respectfully requested.

**No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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